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10/752,435	01/06/2004	Lee Bolduc	9494.18510	3762

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EXAMINER

SEVERSON, RYAN J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/752,435

Applicant(s)

BOLDUC ET AL.

Examiner

Ryan Severson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "X and sinusoidal patterns of the prescribed weave" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
2. The drawings are objected to because of the following minor informalities: in figure 1, reference numeral 24, the end ring, is pointing to the rings otherwise designated with reference numeral 22; and in figure 4, each of reference numerals 26, the fastening region, are pointing to the radiopaque markers otherwise designated by reference numeral 30.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Reference Numerals 32 (Page 9, Line 11) and 42 (Page 10, Line 35).
4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The use of the trademarks "Kevlar" and "Vectran" (Page 9, Line 6 and Page 10, Line 29) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 12 and 13 contain the trademark/trade names "Kevlar" and "Vectran". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the

requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the "prescribed constituent" and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 6-8, 16-17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Solovay (5,769,884). Solovay reference discloses the invention substantially as claimed, including a prosthesis comprising a trunk (10) with a "prosthetic material" (30) and a "scaffold" (20) that supports the prosthetic material, the trunk having a "main body region" (13) and a "fastening region" (12) configured differently than the main body region and capable of receiving and retaining at least one fastener.

Regarding claim 2, the fastening region (12) is an end region of the trunk (see Figure 5).

Regarding claim 3, the end region includes a stent ring (24) sized to provide a seal between the end region and the adjoining tissue (see also Column 3, Lines 51-59).

Regarding claim 4, the prosthetic material in the fastening region (12) is different than a prosthetic material in the main body region (13) in that it is shaped differently.

Regarding claim 6, the prosthetic material in the fastening region (12) includes a weave pattern not present in the main body region (13) (see Figure 5C). Differently sized strips in the weave are present in the fastening region than in the main body region, therefore the weave pattern of the fastening region does not exist in the main body region.

Regarding claim 7, Solovay reference discloses that the weave pattern can be made to achieve the desired porosities (see Column 7, Lines 45-47). Therefore, the weave pattern is capable of being formed with a denser weave in the fastening regions than in the main body region.

Regarding claim 8, the prescribed weave pattern comprises an "X-pattern" (see Figure 5C).

Regarding claim 16, the scaffolding (20) is a "self-expanding material" (see Column 7, Lines 25-28).

Regarding claim 17, a malleable material is defined as a material being capable of being shaped, bent, or drawn out. Therefore, a self-expanding stent (scaffolding) is capable of being *bent* or *shaped* to match the contours of the lumen it is placed in.

Regarding claim 19, the prosthetic material can be "ePTFE" (see Column 7, Lines 4-9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) as applied to claim 4 above, and further in view of Lentz (5,522,881).

Solovay reference discloses the invention substantially as claimed including a prosthesis comprising a trunk (10) with a "prosthetic material" (30) and a "scaffold" (20) that supports the prosthetic material, the trunk having a "main body region" (13) and a "fastening region" (12) configured differently than the main body region and capable of receiving and retaining at least one fastener. Solovay reference also discloses the prosthetic material in the fastening region (12) is different than a prosthetic material in the main body region (13) in that it is shaped differently. However, Solovay reference does not disclose having more layers in the fastening region than the main body region. Attention is drawn to Lentz reference, which teaches that the end regions of the

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prosthetic material be folded over to form multiple layers (see Figure 4) at the ends to provide a better seal and more secure hold between the prosthetic material and the lumen it is placed within. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to fold over the ends of the fastening region of Solovay reference to form multiple layers, as taught by Lentz reference, to provide a better seal and more secure hold between the prosthetic material and the lumen it is placed within.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) as applied to claim 6 above, and further in view of Schmitt (6,090,137). Solovay reference discloses the invention substantially as claimed including a prosthesis comprising a trunk (10) with a "prosthetic material" (30) and a "scaffold" (20) that supports the prosthetic material, the trunk having a "main body region" (13) and a "fastening region" (12) configured differently than the main body region and capable of receiving and retaining at least one fastener. Solovay reference also discloses the prosthetic material in the fastening region (12) is different than a prosthetic material in the main body region (13) in that it is shaped differently. Solovay reference further discloses the prosthetic material in the fastening region (12) includes a weave pattern not present in the main body region (13). However, Solovay reference does not disclose that the weave pattern comprises a sinusoidal pattern. Attention is drawn to Schmitt reference, which teaches the use of a sinusoidal pattern to form a tubular prosthesis (see Figure 2) to provide increased radial strength in the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to make the weave pattern of Solovay reference with a sinusoidal pattern, as taught by Schmitt reference, to provide increased radial strength in the prosthesis.

11. Claims 10, 11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) as applied to claim 4 above, and further in view of Lentz (5,522,881). Solovay reference discloses the invention substantially as claimed including a prosthesis comprising a trunk (10) with a "prosthetic material" (30) and a "scaffold" (20) that supports the prosthetic material, the trunk having a "main body region" (13) and a "fastening region" (12) configured differently than the main body region and capable of receiving and retaining at least one fastener. Solovay reference also discloses the prosthetic material in the fastening region (12) is different than a prosthetic material in the main body region (13) in that it is shaped differently. However, Solovay reference does not disclose that a metallic constituent is interwoven with the main body region but not present in the main body region. Attention is drawn to Lentz reference, which teaches a constituent (28) that is a metallic stent (see Column 3, Lines 34-39) and is placed between the layers of the prosthetic material in the fastening region and not present in the main body (see Figure 4) to provide an increased radial force to secure the prosthetic material to the wall of the lumen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the metallic prescribed constituent (stent) in the manner as taught by Lentz reference with the prosthetic device of Solovay reference to provide an increased radial force to secure the prosthetic material to the wall of the lumen.

Regarding claim 14, the term "interwoven" is defined as linked or locked closely together. The stent of Lentz reference is, therefore, capable of being linked with the main body portion because it is placed between layers of the fastening region, which are connected directly to the main body region (see Figure 4).

12. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) as applied to claim 1 above, and further in view of Taheri et al. (5,591,195). Solovay reference discloses the invention substantially as claimed, including a prosthesis comprising a trunk (10) with a "prosthetic material" (30) and a "scaffold" (20) that supports the prosthetic material, the trunk having a "main body region" (13) and a "fastening region" (12) configured differently than the main body region and capable of receiving and retaining at least one fastener. However, Solovay reference does not disclose the scaffold be configured differently in the fastening region than in the body region. Attention is drawn to Taheri et al. reference, which teaches the scaffolding configuration under the prosthetic material is different in the fastening region from the main body region (see Figure 1) to provide a radial fastening force in the fastening region and prevent kinking of the prosthetic material in the main body region.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the scaffold of Solovay reference in that manner taught by Taheri et al. reference to provide a radial fastening force in the fastening region and prevent kinking of the prosthetic material in the main body region.

13. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) as applied to claim 1 above, and further in view of Rothermel et al.

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(4,255,820). Solovay reference discloses the invention substantially as claimed, including a prosthesis comprising a trunk (10) with a "prosthetic material" (30) and a "scaffold" (20) that supports the prosthetic material, the trunk having a "main body region" (13) and a "fastening region" (12) configured differently than the main body region and capable of receiving and retaining at least one fastener. However, Solovay reference does not disclose the prosthetic material includes polyester. Attention is drawn to Rothermel et al. reference, which teaches polyester fibers can be used to form a tubular woven member to provide a biocompatible material with sufficient strength to provide long-term support to the lumen it is implanted within. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the prosthetic material of Solovay reference of polyester, as taught by Rothermel et al. reference, to provide a biocompatible material with sufficient strength to provide long-term support to the lumen it is implanted within.

14. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) as applied to claim 1 above, and further in view of Bolduc et al. (5,810,882). Solovay reference discloses the invention substantially as claimed, including a prosthesis comprising a trunk (10) with a "prosthetic material" (30) and a "scaffold" (20) that supports the prosthetic material, the trunk having a "main body region" (13) and a "fastening region" (12) configured differently than the main body region and capable of receiving and retaining at least one fastener. However, Solovay reference does not disclose a helical fastener be used in combination with the prosthesis. Attention is drawn to Bolduc et al., which teaches the use of a helical fastener to attach a mesh to

tissue for a secure attachment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the helical fastener of Bolduc et al. reference in combination with the prosthetic device of Solovay reference to attach the prosthetic material to the tissue of the inner lumen for a secure attachment.

15. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) as applied to claim 1 above, and further in view of Pinchuk (5,855,598).

Solovay reference discloses the invention substantially as claimed, including a prosthesis comprising a trunk (10) with a "prosthetic material" (30) and a "scaffold" (20) that supports the prosthetic material, the trunk having a "main body region" (13) and a "fastening region" (12) configured differently than the main body region and capable of receiving and retaining at least one fastener. However, Solovay reference does not disclose the body region includes a socket sized and configured to couple an auxiliary prosthesis structure to the trunk. Attention is drawn to Pinchuk reference, which teaches the body portion of a prosthesis acts as a socket to receive an auxiliary prosthesis structure and couple it to the trunk (see Figures 19-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the main body portion of Solovay reference as a socket, as taught by Pinchuk reference, to receive an auxiliary prosthesis structure and couple it to the trunk.

16. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) in view of Pinchuk (5,855,598). Solovay reference discloses the invention substantially as claimed, including a prosthesis system comprising: a "first prosthesis" with a "prosthetic material" (30) and a "scaffold" (20) that supports the prosthetic

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material, the trunk including a “main body region” (13) and a “fastening region” (12) configured differently than the main body region capable of receiving and retaining at least one fastener. However, Solovay reference does not disclose that the body region includes a socket region and the system include an auxiliary prosthesis. Attention is drawn to Pinchuk reference, which teaches the body portion of a prosthesis acts as a socket to receive an auxiliary prosthesis structure (see Figures 9-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the main body portion of Solovay reference as a socket to receive an auxiliary prosthesis structure as taught by Pinchuk reference.

17. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) in view of Bolduc et al. (5,810,882). Solovay reference discloses *providing a prosthesis* comprising a “prosthetic material” (30) and a “scaffold” (20) that supports the prosthetic material, the trunk including a “main body region” (13) and a “fastening region” (12) configured differently than the main body region capable of receiving and retaining at least one fastener. Solovay reference also discloses *deploying the prosthesis* in the tissue region (see Column 3, Lines 60-63). However, Solovay reference does not disclose *implanting at least one fastener* in the fastening region. Attention is drawn to Bolduc et al. reference, which teaches a fastener is implanted to secure a mesh to tissue. Therefore, it would have been obvious to one of ordinary skill in the art to add the step of implanting a fastener, as taught by Bolduc et al. reference, to the process of deploying the prosthesis of Solovay reference to secure the prosthetic material to the tissue of the lumen wall.

18. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) in view of Bolduc et al. (5,810,882) as applied to claim 23 above, and further in view of Pinchuk (5,855,598). Solovay in combination with Bolduc et al. references disclose the process of providing a prosthesis, deploying the prosthesis in the tissue region, and implanting a fastener. However, Solovay and Bolduc et al. references do not disclose the step of deploying an auxiliary prosthesis and coupling it to the trunk of the main prosthesis. Attention is drawn to Pinchuk reference, which teaches an auxiliary prosthesis is deployed and coupled to a primary prosthesis to provide support for a length of a lumen beyond the length of the primary prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to deploy an auxiliary prosthesis and couple it to the main prosthesis, as taught by Pinchuk reference, upon the completion of the deployment of a main prosthesis and implantation of a fastener, as disclosed by Solovay and Bolduc et al. references, to provide support for a length of a lumen beyond the length of the primary prosthesis.

19. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) in view of Bolduc et al. (5,810,882) as applied to claim 23 above, and further in view of Pinchuk (5,855,598). Solovay in combination with Bolduc et al. references disclose the process of providing a prosthesis, deploying the prosthesis in the tissue region, and implanting a fastener. However, Solovay and Bolduc et al. references do not disclose the prosthesis is deployed using an intravascular tool. Attention is drawn to Pinchuk reference, which teaches the prosthesis be deployed

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using an intravascular tool (see Column 6, Lines 20-24) to provide a minimally invasive procedure to cut down on recovery time after the procedure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to deploy the prosthesis of Solovay reference with an intravascular tool, as taught by Pinchuk reference, to provide a minimally invasive procedure to cut down on recovery time after the procedure.

Regarding claim 26, Pinchuk reference discloses deploying an auxiliary prosthesis after deployment of a primary prosthesis (see description of claim 24 also).

20. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay (5,769,884) in view of Bolduc et al. (5,810,882) as applied to claim 23 above, and further in view of Pinchuk (5,855,598). Solovay in combination with Bolduc et al. references disclose the process of providing a prosthesis, deploying the prosthesis in the tissue region, and implanting a fastener. However, Solovay and Bolduc et al. references do not disclose the tissue region contains an aneurysm. Attention is drawn to Pinchuk reference, which teaches the use of the prosthetic device to treat an aneurysm (see Figures 18-21 and Column 11, Lines 17-19). Therefore, it would have been obvious to one of ordinary skill in the art to use the prosthesis of Solovay and the fasteners of Bolduc et al. to treat an aneurysm as taught by Pinchuk.

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ryan Severson
October 5, 2006



ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

10/15/06